510(k) Summary

K041138

1. **SUBMITTER:**

   Submitted on Behalf of:

▪ Company Name:	CooperVision Manufacturing, Ltd.
▪ Address:	Unit 2, South Point Hamble SO3 4RF Southampton UK
▪ Phone:	011 44 2380 605200
▪ Fax:	011 44 2380 605299

2. **CONTACT PERSON:** Bonnie Tsymbal

▪ Company Name:	CooperVision, Inc.
▪ Address:	711 North Road Scottsville, NY 14546
▪ Phone:	(585) 264-3210
▪ Fax:	(585) 889-5688

3. **DATE SUMMARY PREPARED:** April 28, 2004

4. **DEVICE IDENTIFICATION:**

▪ Trade Name:	Leo Colors, Leo Aspheric Colors and Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lens
▪ Common Name:	Hydrophilic Soft Contact Lens
▪ Classification	Lenses, Soft Contact, Daily Wear 86LPL
▪ Device Classification:	Class II (21 CFR 886.5925)

5. **DEVICE DESCRIPTION:**

The Leo Colors and Leo Aspheric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are available as spherical lenses. Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are available as astigmatic lenses. The lens material, methafilcon A, is a random co-polymer of hydroxyethylmethacrylate and methacrylic acid, which is cross-linked with ethyleneglycol dimethacrylate. The lenses are made by modifying the uncolored methafilcon A base lens by affixing colorants on that portion of the front surface that corresponds to the iris. The colorants Titanium Dioxide, C.I. Reactive Blue 21, C.I. Reactive Red 180, C.I. Reactive Yellow 15, and C.I Reactive Black 5 are listed in 21 CFR Part 73.

Chemical Name	CI Number	CFR#
Titanium dioxide	77891	73.3126
Poly (hydroxyethyl methacrylate)-dye copolymer	C.I. Reactive Blue 21	73.3121
Poly (hydroxyethyl methacrylate)-dye copolymer	C.I. Reactive Red 180	73.3121
Poly (hydroxyethyl methacrylate)-dye copolymer	C.I. Reactive Yellow 15	73.3121
Poly (hydroxyethyl methacrylate)-dye copolymer	C.I Reactive Black 5	73.3121

6. INTENDED USE

1. Leo Colors and Leo Aspheric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

2. Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for the management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less or for occlusive therapy for conditions such as diplopia, amblyopia an extreme photophobia.

Frequent/Planned Replacement Wear

When prescribed for Frequent/Planned Replacement Wear, the Leo Colors, Leo Aspheric Colors and Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

Disposable Wear

When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for daily wear (single use). Patients should be instructed to discard the lenses at each removal.

7. PREDICATE DEVICE:

The Leo Colors and Leo Aspheric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses for daily wear manufactured by CooperVision Manufacturing Ltd. Is equivalent to the Frequency 55 (methafilcon A) Soft (hydrophilic) Contact Lens (K971164) and Frequency Colors and Expressions (methafilcon A) Soft (hydrophilic) Contact Lenses for daily wear (K001090)

As the methafilcon A base lens is produced at the same manufacturing facility as the Frequency 55, Frequency Colors and Expressions, the physical, optical and chemical properties are the same. They are all in Lens Group 4, high water ionic polymer as established by FDA and located in the May 1994 Guidance Document for Daily Wear Contact Lenses.

	Leo Colors **Subject Device**	**Frequency 55** **Predicate Device** **K971164**	**Frequency Colors** **Predicate Device** **K001090**
Material	Methafilcon A	Equivalent	Equivalent
Material Classification	Hydrophilic lens, Group 4	Equivalent	Equivalent
Indication for use	Daily Wear Myopia, hyperopia and astigmatism	Daily Wear Myopia and hyperopia	Daily Wear Myopia, hyperopia and astigmatism
Water Content	55%	Equivalent	Equivalent
Light transmittance	>90.0%	Equivalent	Equivalent
Dk (35°)	15.04	Equivalent	Equivalent
Index of Refraction	1.41	Equivalent	Equivalent
Powers	-20.00 to +20.00D	Equivalent	Equivalent
Colorants	Titanium Dioxide CI Reactive Blue 21 CI Reactive Red 180 CI Reactive Yellow 15 CI Reactive Black 5.	CI Reactive Blue 4	Carbozale violet chromim oxide green dihydrodinaphto brown dihydrodioxo yellow phthalocyanine green iron oxide red iron oxide brown iron oxide black phthalocyanine blue and titanium dioxide
Tint Process	Ink jetting post lens forming.	In-monomer tint	Pad printing post lens forming
Manufacturing Method	Molded or FIPS II	Molded	Molded or FIPS II

8. PRECLINICAL INFORMATION

The results of toxicology testing, including Ocular Irritation, Cytoxicity and Systemic Toxicity have demonstrated that the subject lens is non-toxic.

A leachability study was conducted to assess the color fastness of the listed dyes used to tint the Leo Colors, Leo Aspheric Colors and Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses. The study demonstrates that after two weeks of extraction at 37°C in saline, undetectable levels (<1ppm) of dye were observed in the extraction solution.

The physical, optical and chemical properties of the subject lens are equivalent to the predicate device.

9. CLINICAL DATA

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the Leo Colors, Lens Aspheric Colors and Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses. This determination was based on the following:

- The Leo Colors, Lens Aspheric Colors and Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses were demonstrated to be substantially equivalent to the predicate Frequency 55 (methafilcon A) Soft (hydrophilic) Contact Lens (K971164) and (K973063)

- The Leo Colors, Lens Aspheric Colors and Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses were demonstrated to be substantially equivalent to the predicate Frequency Colors and Expressions (methafilcon A) Soft (hydrophilic) Contact Lens (K001090).

10. CONCLUSION

The information provided in this 510(k) established that the Leo Colors, Lens Aspheric Colors and Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses is equivalent in optical, chemical and physical properties of the predicate device and does not raise any questions of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Cooper Vision
c/o Ms. Bonnie Tsymbal
Manager, Regulatory Affairs
711 North Road
Scottsville, NY 14546

Re: K041138
Trade/Device Name: Leo Colors, Leo Aspheric Colors and Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL; MVN
Dated: April 29, 2004
Received: May 3, 2004

Dear Ms. Tsymbal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CooperVision
Regulatory Affairs
711 North Road
Scottsville, NY 14546
(585) 385-6810
Fax: (585) 889-5688

Indication for Use Statement

Device Name: Leo Colors (methafilcon A) Soft (hydrophilic) Contact Lenses
Leo Aspheric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses
Leo Toric Colors (methafilcon A) Soft (hydrophilic) Contact Lenses

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Disposable Wear

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PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K041138

Prescription Use ✓ AND/OR Over-The-Counter ____
(Per 21 CFR 801.109)